CHAPTER 570.000: THE MANUFACTURE, COLLECTION, AND BOTTLING OF WATER AND CARBONATED NON-ALCOHOLIC BEVERAGES

570.001: Purpose

The purpose of these regulations is to establish standards for the manufacture, collection, bottling and labeling of bottled water and carbonated non-alcoholic beverages. 105 CMR 570.000 shall be liberally construed and applied to promote the underlying purpose of protecting the public health.

570.002: Scope

105 CMR 570.000 applies to all persons within Massachusetts who manufacture or bottle carbonated non-alcoholic beverages or bottled water, whether carbonated or non-carbonated, for human consumption and to all persons engaged in such business outside Massachusetts who wish to sell such products within Massachusetts. Certain regulations, where specified, apply only to bottled water and not to carbonated non-alcoholic beverages.

570.003: Definitions

As used in 105 CMR 570.000, the following terms shall have the following meanings:

Approved laboratory means a laboratory certified by the Massachusetts Department of Environmental Protection (DEP) or certified by the U.S. Environmental Protection Agency (EPA) or approved by another state or jurisdiction to perform drinking water analyses in accordance with standard water quality testing methods.

Approved source when used in reference to a plant's product or water used in the plant's operations means the source(s) of the water and the water therefrom, when the source has been inspected and approved as specified in 105 CMR 570.007 and the water sampled, analyzed, and found to be of a safe and sanitary quality in accordance with 105 CMR 570.008 and 570.009.

Artesian water means "artesian water" as defined in 21 CFR § 165.110(a)(2)(i).

Board of health means the appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within the Commonwealth having the usual powers and duties of the board of health of a city or town.

Bottled water means "bottled drinking water" as defined in 21 CFR § 129.3(b).

Bulk water means water intended for potable uses which is transported via tanker truck or an equivalent means from one area to another for the purpose of treatment, packaging and/or human consumption.

CFR means the Code of Federal Regulations.

Carbonated non-alcoholic beverage means a carbonated beverage of any flavor containing no alcohol and includes but is not limited to soda water, sparkling water made with added carbon dioxide, seltzer water, carbonated water, and tonic water.

Commissioner means the Commissioner of Public Health.

DEP means the Massachusetts Department of Environmental Protection.

Department means the Massachusetts Department of Public Health.

Division means the Division of Food and Drugs of the Massachusetts Department of Public Health.

EPA means the U.S. Environmental Protection Agency.

Imminent health hazard or imminent danger to the public health means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance or event creates a situation that requires immediate correction or cessation of operation to prevent harm. This definition may include but is not limited to:
(1) An extended loss of operations water supply;
(2) The use of an unapproved source of water within the plant;
(3) The source water is out of compliance with the quality standard in 105 CMR 570.008(A) in a way that presents an imminent danger to public health;
(4) A failed sewer system or a sewage backup into the plant;
(5) An extended power outage;
(6) The plant has been subject to one or more of the following: flood, fire, chemical exposure, natural disaster and/or other catastrophic event;
(7) An employee has been found to be infected with a communicable disease as described in 105 CMR 570.014; or
(8) Severe unsanitary conditions that threaten to contaminate the source, the plant, a part of the plant or a particular product.
The failure to include other violations, practices, circumstances or events in this definition shall not be construed as a determination that other violations, practices, circumstances or events are not or may not be considered an imminent health hazard.

Label means any display of written, printed or graphic matter on the immediate container of an article.

Labeling means all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

Law includes federal, state and local statutes, ordinances and regulations.

Mineral water means "mineral water" as defined in 21 CFR § 165.110(a)(2)(iii).

Minimal treatment means treatment limited to the use of filters (paper, activated carbon and/or particulate); ozonation; and/or the use of ultraviolet light for disinfection. Any other treatment activity, including but not limited to ion exchange and reverse osmosis, is considered more than minimal treatment.

MOU means the Memorandum of Understanding Between the Department of Public Health and the Department of Environmental Protection for In-State Bottled Water Source Review.

Noncompliance, Failure to comply and Violation each mean any act or failure to act, which constitutes, or results in, one or more of the following:
(1) Engaging in any bottling operation subject to regulation by 105 CMR 570.000 or applicable statute, without a permit, whenever engaging in such an operation requires a permit.
(2) Engaging in any activity prohibited by, or not in compliance with, 105 CMR 570.000, or any order or permit issued or adopted by the Department or the board of health pursuant to 105 CMR 570.000 or applicable statute.
(3) Failing to do, or failing to do in a timely manner, anything required by 105 CMR 570.000, or any order or permit issued or adopted by the Department or the board of health pursuant to 105 CMR 570.000 or applicable statute.

Operations water means "operations water" as defined in 21 CFR § 129.3(f).

Permit holder means the person who holds a permit for bottling water, whether carbonated or non-carbonated, and/or carbonated non-alcoholic beverages.

Person means any individual, partnership, corporation, association or other legal entity.

Person in charge means the individual present in a plant or at a water source who is the supervisor or is otherwise responsible for the operation of the plant or water source at the time of inspection.

Plant means any establishment in which bottled water or bottled carbonated non-alcoholic beverages are bottled/manufactured for shipment or sale.

Product water means "product water" as defined in 21 CFR § 129.3(h).

Public water system means a system for the provision to the public of water for human consumption, as defined by the Safe Drinking Water Act, in compliance with standards of the Massachusetts DEP or in compliance with the comparable standards of the state or foreign country where the public water system is located.

Purified water means "purified water" as defined in 21 CFR § 165.110(a)(2)(iv).

Source approval means approval by the Department, with or without conditions, of a water source, substantial modification of a water source, treatment of source water, and/or substantial modification of treatment of source water, for use in a plant producing bottled water or carbonated non-alcoholic beverages.

Source water means the water taken from a water source prior to its use in bottling water or carbonated non-alcoholic beverages.

Sparkling bottled water means "sparkling bottled water" as defined in 21 CFR § 165.110(a)(2)(v).

Spring water means "spring water" as defined in 21 CFR § 165.110(a)(2)(vi).

Sterile water means "sterile water" as defined in 21 CFR § 165.110(a)(2)(vii).

Substantial modification of a water source or treatment of source water means any deviation from approved plans or specifications affecting capacity, hydraulic conditions, operating units, the functioning of water treatment processes or systems, the source or the quality of water delivered to the plant.

Water source means any ground or surface water body and the site from which the water is withdrawn.

Well water means "well water" as defined in 21 CFR § 165.110(a)(2)(viii).

570.004: Adoption of Federal Regulation 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food

The Department hereby adopts and incorporates by reference the federal regulation 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food, published by the United States Office of the Federal Register, National Archives and Records Administration, Washington, DC (2002), to the extent that it is not inconsistent with specific provisions of 105 CMR 570.000.

570.005: Adoption of Portions of Federal Regulation 21 CFR Part 129: Processing and Bottling of Bottled Drinking Water

The Department hereby adopts and incorporates by reference, for bottled water only, the following provisions of the federal regulation 21 CFR Part 129: Processing and Bottling of Bottled Drinking Water, published by the United States Office of the Federal Register, National Archives and Records Administration, Washington, DC (2002), to the extent that these provisions are not inconsistent with specific provisions of 105 CMR 570.000.
(A) Subpart A - General Provisions;
(B) Subpart B - Buildings and Facilities, sections 129.20, 129.35(a)(4)(iii), and 129.37 only.
(C) Subpart C - Equipment; and
(D) Subpart E - Production and Process Controls.

570.006: Adoption of Portions of Federal Regulation 21 CFR Part 165: Beverages

The Department hereby adopts and incorporates by reference the following provisions of the federal regulation 21 CFR Part 165: Beverages, published by the United States Office of the Federal Register, National Archives and Records Administration, Washington, DC (2002), to the extent that these provisions are not inconsistent with specific provisions of 105 CMR 570.000:

(A) Subpart A - General Provisions, for both bottled water and carbonated non-alcoholic beverages; and
(B) Subpart B - Requirements for Specific Standardized Beverages, subsection 165.110(a) only, for bottled water only.

570.007: Water Source Protection, Treatment and Modification for Bottled Water and Carbonated Non-Alcoholic Beverages

(A) In-State Sources
(1) Each water source shall maintain conformity with 310 CMR 22.00, with any applicable Massachusetts Department of Environmental Protection (DEP) water supply health advisories or guidelines, and, if applicable, with M.G.L. c. 21G.
(2) The Department and DEP shall cooperate in the approval, inspection, and enforcement of requirements for in-state water sources, pursuant to the terms of the MOU.
(3) Each water source shall be located, developed, and protected to ensure that it is not subject to natural or artificial contamination. If necessary, source water may be treated in order to control natural or artificial contamination. Source water treatment must be approved in accordance with 105 CMR 570.007(A)(4) and (5).
(4) Before a water source is used or substantially modified, or the source water is treated or the treatment is substantially modified, or a new source is used in addition to the existing approved source(s), the source owner shall apply to the Department for approval and shall submit information as required by the application form, including but not limited to:
(a) The type of source (e.g. well, spring);
(b) A detailed location of the source;
(c) The owner(s) of the source;
(d) Information about the use and treatment of the source and/or the modification of the source or treatment; and
(e) If the source is a public water system, the information specified in 105 CMR 570.009(A)(1)(c).
(5) The Department will forward that portion of the application relating to the water source to DEP. Based on DEP's recommendation and in accordance with current law, the Department shall notify the owner whether the following are approved:
(a) The water source;
(b) Substantial modification to the water source;
(c) Treatment to bring source water into compliance with the quality standards in 105 CMR 570.008(A); and/or
(d) Substantial modification to source water treatment.
If the Department determines that approval is not appropriate, it shall notify the owner of the modifications that are necessary in order for approval to be granted.
(6) Prior to the sale of products using any new or substantially modified source or new or substantially modified treatment, the bottler shall submit the following information to the Department:
(a) One label for each container size and brand name of the product that is proposed to be sold; and
(b) If the source is not a public water system, or if the source is a public water system that the bottler treats in a way that does not meet the definition of minimal treatment, the results of a

complete chemical, physical, microbiological and radiological analysis of the source water and of each of the different finished products bottled by the plant, as specified in 105 CMR 570.009(A). The analyses shall have been completed within the twelve months prior to the first use of the source water, with the exception of the microbiological analysis, which shall have been performed within the four weeks prior to the first use of the source water.
(7) The bottler shall not sell products manufactured with water from the new or substantially modified source or new or substantially modified treatment until written approval is received from the Department.
(8) The bottler may only use water from a particular water source in bottling bottled water or carbonated non-alcoholic beverages when that source and any treatment of that source have a current approval from the Department.
(9) With respect to the use or substantial modification of a water source, or treatment or substantial modification of treatment of source water, the Department has the authority to commence enforcement proceedings against a water source pursuant to 105 CMR 570.022(F) and 570.023.

(B) Out-of-state and Foreign Sources
(1) Out-of-state and foreign water sources shall be licensed or approved by the government agency having jurisdiction. A copy of the current such license or approval shall be provided to the Department by the bottler upon application and reapplication for a permit, and upon substantial modification of the source or source treatment or the addition of a new source.
(2) Prior to the sale of products using any new or substantially modified source or new or substantially modified treatment, the bottler shall submit to the Department the information specified in 105 CMR 570.007(A)(4) and (6).
(3) The bottler shall not sell products manufactured with water from the new or substantially modified source or new or substantially modified treatment until written approval is received from the Department.

(C) Maintenance of Records. At all times, the plant shall maintain current records of approval of the source water by the government agency having jurisdiction.

570.008: Quality Standards for Bottled Water and Carbonated Non-Alcoholic Beverages

(A) Source Water. All source water shall comply with applicable requirements of 310 CMR 22.00, promulgated by DEP, and with any additional maximum contaminant levels promulgated by EPA and in effect. Source water may be treated to reduce the level of a contaminant or drinking water constituent.

(B) Finished Product
(1) The finished product shall conform to the standards of quality in 21 CFR § 165.110(b).
(2) Finished products, the quality of which is below that prescribed by any standard of quality in 21 CFR § 165.110(b) (i.e. substandard products), shall not be sold or distributed in any manner in Massachusetts.

570.009: Sampling and Testing Requirements

(A) Sampling and Testing Procedures
(1) Source Water. This subsection, 105 CMR 570.009(A)(1), applies to both bottled water and carbonated non-alcoholic beverages, except that subsection 570.009(A)(1)(d) applies only to bottled water.
(a) The raw water from the source shall be sampled immediately after it is withdrawn from the source, and analyzed to characterize its microbiological, physical, radiological and chemical quality. If any of the analyses show the water not to be in compliance with the quality requirements specified in 105 CMR 570.008(A), the water shall be treated to meet those requirements and shall be tested after treatment. Sampling and analysis shall be performed as often as necessary, but at a minimum frequency of:
(i) Once each year for chemical and physical contaminants;
(ii) Once every four years for radiological contaminants; and
(iii) Once each week for microbiological contaminants.
(b) All analyses shall be conducted by an approved laboratory in accordance with the testing and methodological requirements specified by EPA's National Primary and Secondary Drinking Water Regulations (40 CFR Parts 141 and 143).
(c) Plants that use a public water system for source water, without treatment or with only minimal treatment, may satisfy the testing requirements of 105 CMR 570.009(A)(1)(a) and (b) by substituting public water system testing results, or copies of certificates showing full compliance with relevant provisions of the EPA regulations at 40 CFR Parts 141 and 143. Any additional treatment of the source water from a public water system that does not meet the definition of minimal treatment shall require source water analysis pursuant to 105 CMR 570.009(A)(1)(a) and (b); and for bottled water only, submission of results pursuant to 105 CMR 570.009(A)(1) (d).
(d) Bottled water only: Each plant shall submit a copy of the results of all analyses of its source water as specified in 105 CMR 570.009(A)(1)(a) through (c), or copies of certificates as allowed by 105 CMR 570.009(A)(1)(c), to the Department at the same time as it submits its initial application for a permit, and annually thereafter, as follows:
(i) Testing for chemical and physical contaminants performed within the preceding twelve months.
(ii) Testing for radiological contaminants performed within the preceding twelve months, for any year in which radiological testing is required.
(iii) Testing for microbiological contaminants performed within the preceding four weeks.
(2) Finished Product: Bottled Water
(a) Samples of each type of finished bottled water product produced shall be taken by the plant and analyzed by an approved laboratory in the manner and frequency specified in 21 CFR § 129.80.
(b) In addition, if any flavor or color is added to the product during the manufacturing process, a representative sample shall be taken immediately prior to the addition of such flavor or color, at the frequency specified in 21 CFR § 129.80, and the sample shall be analyzed by an approved laboratory in the manner and frequency specified in 21 CFR § 129.80.
(c) The methods of analysis shall be as specified in 21 CFR § 165.110(b).
(d) The plant shall submit a copy of the results of the analyses of its finished products performed in accordance with 105 CMR 570.009(A)(2)(a) through (c) to the Department. Such results shall be submitted at the same time as it submits its initial application for a permit, and annually thereafter, as follows:

(i) Testing for chemical, physical and radiological contaminants performed within the preceding twelve months, and
(ii) Testing for microbiological contaminants performed within the preceding four weeks.
(3) Finished Product: Carbonated Non-alcoholic Beverages
(a) Samples of each type of finished carbonated non-alcoholic beverage product shall be taken and analyzed as frequently as necessary to ensure that all products meet the quality standards in 105 CMR 570.008(B).
(b) Routine test results need not be submitted to the Department, but all results shall be maintained by the plant as required by 105 CMR 570.009(D).

(B) Additional Testing of Bottled Water and Carbonated Non-alcoholic Beverages
(1) Notwithstanding any other provisions of 105 CMR 570.000, the Department may require any bottler of bottled water or carbonated non-alcoholic beverages or any applicant for a permit to test and submit results to the Department for any substance at any time when the Department has reason to believe that the substance may be present in a water source or in a finished product and may threaten public health.
(2) Whenever a bottler or permit applicant has reason to believe that a substance may be present in a water source or in a finished product and may threaten public health, the bottler or permit applicant shall:
(a) Notify the Department within 24 hours;
(b) Test the source water or finished product for the substance at a frequency determined by the Department;
(c) Submit all test results to the Department, and direct the laboratory conducting the testing to submit all test results to the Department, within 24 hours of obtaining the test results; and
(d) Follow the Department's instructions as to whether and under what conditions bottling operations may continue until the problem is resolved.

(C) Unexpected Noncompliance with Quality Standards: Bottled Water or Carbonated Non-alcoholic Beverages
(1) In-state Plants
(a) Source Water. When an in-state plant receives any test result indicating that its water source is not in compliance with any Maximum Contaminant Level listed in 310 CMR 22.00, or with any other Maximum Contaminant Level promulgated by EPA and in effect, it shall:
(i) Notify the Department within 24 hours;
(ii) Test the source water at a frequency determined by the Department;
(iii) Submit all test results to the Department, and direct the laboratory conducting the testing to submit all test results to the Department, within 24 hours of obtaining the test results; and
(iv) Follow the Department's instructions as to whether and under what conditions bottling operations may continue until the problem is resolved.
(b) Finished Products. When an in-state plant receives any confirmed test result indicating that any of its finished products is not in compliance with any standard of quality in 21 CFR § 165.110(b), it shall:
(i) Immediately cease all operations until the Department determines that the finished product is in compliance with all applicable quality standards;
(ii) Notify the Department within 24 hours;
(iii) Conduct appropriate tests at a frequency determined by the Department; and

(iv) Submit all test results to the Department, and direct any laboratory conducting the testing to submit all test results to the Department, within 24 hours of obtaining the test results.
(2) Out-of-state Plants. When an out-of-state plant receives any confirmed test result indicating that any of its finished products is not in compliance with any standard of quality in 21 CFR § 165.110(b), it shall notify the Department within 24 hours.

(D) Maintenance of Test Results by Plants Producing Bottled Water or Carbonated Non-alcoholic Beverages. Results of all sampling and analysis shall be maintained for five years in a separate file at the plant and shall be made available to the inspectors of the Department, DEP as the Department's designee, and/or the local board of health during an inspection or upon request.

570.010: Product Recall

(A) Each operator of a bottled water or carbonated non-alcoholic beverage plant shall develop and maintain on file a current written contingency plan for use in initiating and accomplishing a product recall in accordance with 21 CFR §§ 7.40 through 7.49, 7.53 and 7.55. The plan shall include procedures for the notification of the Department, consumer notification, and recall of the product.

(B) The plant shall use sufficient coding of bottled products to make possible positive lot identification and to facilitate effective recall of all violative lots. The code shall be designed to remain affixed to the container during use.

(C) The plant shall maintain such product distribution records as are necessary to enable location of products if a recall is initiated. These records shall be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least 5 years.

(D) The plant shall implement the recall procedures as necessary with respect to any product for which the bottler or the Department knows or has reason to believe that circumstances exist that may adversely affect its safety for the consumer.

(E) A bottler who knows that the standard of quality has been violated or has reason to believe that circumstances exist which may adversely affect the safety of bottled products, including but not limited to source contamination, spills, accidents, natural disasters, or breakdowns in treatment, shall notify the Department within 24 hours of learning of the violation or circumstances. Any in-state bottler shall also notify the board of health, and if the problem is believed to be connected with the water source, the in-state bottler shall notify DEP.

(F) If the Department determines that the circumstances present an imminent health hazard and that a form of consumer notice and/or product recall can effectively avoid or significantly minimize the threat to public health, the Department may advise the bottler:
(1) To initiate a level of product recall approved by the Department, and/or
(2) If appropriate, to issue a form of notification to consumers.
(a) The bottler shall be responsible for disseminating the notice in a timely manner and in a form designed to inform consumers who could be affected by the problem.

(b) The bottler shall where appropriate provide notice to radio and television media and/or to the newspaper(s) serving the potentially affected public, and/or shall directly notify affected users when doing so will effectively avoid or minimize the risk to health.

(G) Product recalls shall conform to the procedures and policies of 21 CFR Part 7.

570.011: Bulk Storage and Transportation of Water

(A) General. A bottled water or carbonated non-alcoholic beverage plant shall not accept water for use in its products unless the plant and/or the bulk water transporter, as appropriate, comply with the following requirements.
(1) Bulk tanker trucks, storage tanks and related equipment shall be cleaned, sanitized and inspected internally for integrity on a routine basis in compliance with the sanitary standards in 21 CFR Parts 110 and 129. A record of all cleaning and sanitizing showing the date, time, place and signature or initials of the person doing the work shall be maintained with the vehicle or storage tank. If someone other than an employee of the permit holder does the work, a copy of the record shall be given to the permit holder and kept at the plant for at least 6 months. The plant shall provide these records to the Department upon request.
(2) Equipment used for transport of bulk water shall not be used, and shall not have been used previously, for any non-food product. Such equipment shall not be used for any dairy product or non-beverage food except in an emergency. If the equipment is used for any food or beverage other than bulk water, it shall be cleaned and sanitized as required by 21 CFR Parts 110 and 129 immediately before the water is loaded.
(3) Bulk tanker trucks transporting water to a plant from sources of supply other than those owned by the plant shall be marked with the name and address of the bulk water hauler. For each shipment, a shipping statement shall be prepared containing at least the following information:
(a) Name and address of the owner of the water source and site of the water source;
(b) Date of loading;
(c) Gallons of source water delivered;
(d) Date and time delivered at the plant.
The shipping statement shall be retained on file for at least 6 months at the plant.
(4) Upon filling, all access points to the contents of the tanker shall be sealed with a tamper-evident seal printed with a unique identifier. The seal may be removed only by the receiving plant.

(B) Responsibility of Permit Holder. The permit holder shall assure that its bulk water supplier and transporter comply with the appropriate sanitary requirements in 21 CFR Parts 110 and 129.

570.012: Labeling Requirements

(A) General Requirements. All bottled water and carbonated non-alcoholic beverages shall comply with applicable requirements of the federal Food Labeling regulations, 21 CFR Part 101. Among other things, this Part includes the federal regulations governing nutrition labeling, nutrient content claims, and health claims. When the Department receives a complaint alleging a violation of any provision of 21 CFR Part 101 with respect to a food that is at any time in the

course of interstate commerce, the Department may refer the complainant to the U.S. Food and Drug Administration.

(B) Standards of Identity for Bottled Water
(1) Bottled water labeling shall comply with the standards of identity in 21 CFR § 165.110(a).
(2) Any product that does not comply with the standards of identity in 21 CFR § 165.110(a) shall not be marketed in Massachusetts, unless prior to marketing the product the permit holder submits to the Department current, written authorization from the U.S. Food and Drug Administration (FDA) allowing the marketing of such product.

(C) Additional Labeling Requirements for Bottled Water. All bottled water shall comply with the following additional labeling requirements.
(1) Source. The label shall state:
(a) The type of water source (such as well, spring).
(b) The location of the water source: municipality, state, and country if not the U.S.
(c) When bottled water comes from a community water system, as defined in 40 CFR § 141.2, except when it has been treated to meet the definition in 21 CFR § 165.110 (a)(2)(iv) (purified water) or 21 CFR § 165.110(a)(2)(vii) (sterile water) and is labeled as such, the label shall state "from a community water system" or, alternatively, "from a municipal source" as appropriate, on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.
(d) If more than one water source is used in the final product, the label shall clearly state the type and location of all water sources used.
(2) Spring
(a) The term "spring", "springs" or "spring water" shall not be used as a product name or a brand name on a label unless the water source meets the definition of spring water in 21 CFR § 165.110(a)(2)(vi).
(b) If the word "spring" appears in the company name and the water source is not a spring, the word(s) designating the type of source shall be no smaller than one half the size of the word "spring" in the company name.

570.013: Supplemental Regulations for Processing and Bottling of Bottled Water and Carbonated Non-alcoholic Beverages

(A) Operations Water. If different from the product water supply, the operations water supply shall be obtained from an approved source. Records of approval of the source of the operations water by the government agency having jurisdiction shall be maintained on file at the plant.

(B) Non-Food Uses: Prohibition. Water or carbonated non-alcoholic beverages intended for bottling shall not be stored, transported, processed or bottled through equipment or lines used for any non-food product.

(C) Multi-Use Equipment. Water intended for bottling water or carbonated non-alcoholic beverages shall not be stored, transported, processed or bottled through equipment or lines used

for any dairy product or non-beverage food, except that filling equipment may be used for dairy products and non-beverage foods in accordance with the following requirements.
(1) When filling equipment designed for cleaning in place is utilized for dairy products or non-beverage foods, such equipment shall be thoroughly cleaned and sanitized in place in accordance with procedures specified by the manufacturer and in 21 CFR Part 129 prior to being used for bottled water.
(2) Fillers not designed for cleaning in place shall be completely disassembled for cleaning and sanitizing prior to being used for bottled water.

(D) Ozone
(1) Where ozone is used as a germicidal agent, all gaskets, o-rings and similar flexible material shall be made of silicone rubber, teflon or other ozone resistant material. These flexible parts shall be replaced whenever they show evidence of surface deterioration.
(2) If ozone is used as an antimicrobial disinfectant in the bottling process, it shall be used as specified in 21 CFR Part 184.

(E) Sanitation Standard Operating Procedure (SSOP). Each permit holder shall develop and implement a written Sanitation Standard Operating Procedure (SSOP), and shall make it available to inspectors of the Department and/or the local board of health during an inspection or upon request. The SSOP shall be updated as necessary and shall at a minimum address the following areas:
(1) Safety of the plant's operations water;
(2) Construction and condition of, and cleaning procedures for, the plant and all equipment, including but not limited to pipelines, storage tanks, fillers and bottle washing equipment;
(3) Prevention of cross-contamination;
(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
(5) Protection of packaging and product contact surfaces from contamination;
(6) Proper labeling of all toxic substances in the plant;
(7) Sanitization procedures;
(8) Bottle washing procedures;
(9) Employee health and hygiene;
(10) Employee training;
(11) Exclusion of pests; and
(12) Procedures for daily monitoring and recording compliance with the SSOP.

(F) Retention of Records. All records required by 21 CFR Part 129 or 105 CMR 570.000 shall be maintained at the plant for not less than 2 years, unless a different requirement is specifically stated elsewhere in 105 CMR 570.000.

570.014: Prevention of Disease Transmission by Employees

(A) In accordance with 21 CFR § 110.10, it is the responsibility of the permit holder of a bottled water or carbonated non-alcoholic beverage plant to protect the integrity of bottled products by:
(1) Developing and implementing a plan for employee health and hygiene (as part of the SSOP developed pursuant to 105 CMR 570.013(E)) that ensures that all personnel report to their

supervisors illnesses or health conditions through which there is a reasonable possibility of products, product-contact surfaces or packaging materials becoming contaminated; and
(2) Taking appropriate protective steps.

(B) When the permit holder, person in charge, or manager of a plant knows or has reasonable cause to believe that an employee has contracted a disease transmissible through food or food products or has become a carrier of such a disease, he or she shall immediately notify the Director of the Food Protection Program in the Division and, if the plant is in Massachusetts, immediately notify the board of health.

(C) When the Department or board of health knows or has reasonable cause to believe that an employee has contracted a disease transmissible through food or food products or has become a carrier of such a disease, it is authorized to:
(1) Secure a confidential medical history of the suspected employee and make other investigations as deemed appropriate; and
(2) Take any other action required by 105 CMR 300.000: Reportable Diseases and Isolation and Quarantine Requirements.

(D) The board of health shall immediately notify the Director of the Food Protection Program in the Division of suspected disease transmission, and shall keep the Director informed until any investigation is completed.

(E) The Commissioner or his or her designee, on his or her own initiative or at the request of a local board of health, may require any employee whose duties actually involve the handling of products or product-contact surfaces to submit to a medical examination, which may include the taking of samples of body fluids, secretions or excretions, whenever said Commissioner or designee has reason to believe that such examination is necessary for the protection of the public health. The examination shall be without charge to the person examined and at the expense of the Department or of the board of health requesting it.

(F) Any employee who fails to cooperate with any medical or laboratory examination ordered by the Commissioner or his or her designee shall immediately be excluded from the performance of duties involving the handling of products or product-contact surfaces.

(G) In addition, the Department or the board of health, where applicable, may issue an order instituting one or more of the following control measures:
(1) Restriction of particular employees' services to specific areas and tasks in the plant that present no risk of transmitting the disease;
(2) Excluding particular employees from the plant; or
(3) Closing the plant by summarily suspending the permit in accordance with 105 CMR 570.022(A).

(H) The following diseases or disease organisms are known to be transmissible through food or food products:
(1) Salmonella Typhi
(2) Shigella spp.

(3) Escherichia coli O157:H7 and other Enterohemorrhagic E. coli (EHEC)
(4) Hepatitis A virus
(5) Entamoeba histolytica
(6) Camplylobacter spp.
(7) Vibrio spp.
(8) Cryptosporidium spp.
(9) Giardia spp.
(10) Hemolytic Uremic Syndrome
(11) Salmonella spp. (non-typhi)
(12) Yersinia enterocolitica
(13) Cyclospora cayetanensis
This list is not intended to be exclusive, and the Department may, in a given case, determine that a risk of transmission exists from a disease not specified above.

[570.015: RESERVED]
570.016: General Administration

(A) Enforcement Policy. The following provisions shall cover the administration and enforcement of 105 CMR 570.000.

(B) The purpose of the enforcement program is to promote the protection of the public health by:
(1) Ensuring compliance with regulations and conditions of holding a permit or source approval;
(2) Obtaining prompt correction of violations and adverse quality conditions that may affect public health;
(3) Deterring future violations and occurrences of conditions adverse to public health; and
(4) Encouraging improvement of good manufacturing practices for individual permit holders, and by example, for the industry, including prompt identification and reporting of potential health or sanitation problems.

(C) The Department may from time to time publish interpretations of 105 CMR 570.000 and guidelines as necessary to promote uniform application of 105 CMR 570.000, and may make them available to those persons holding permits or source approvals under 105 CMR 570.000. The Department may advise permit holders, source owners or local boards of health on particular questions regarding the interpretation of 105 CMR 570.000.

(D) The Department or the board of health may enforce 105 CMR 570.000 by issuing an order to correct violations or by commencing an administrative enforcement action pursuant to 105 CMR 570.022 and 570.023.

570.017: Permit

(A) No person shall engage within Massachusetts in the business of manufacturing or bottling carbonated non-alcoholic beverages or water, whether carbonated or non-carbonated, for human consumption without a valid permit from the board of health of the city or town where the plant is located. No person shall engage in such business in violation of the terms of a valid permit or the requirements of 105 CMR 570.000.

(B) No person engaged outside Massachusetts in the business of manufacturing or bottling carbonated non-alcoholic beverages or water, whether carbonated or non-carbonated, for human consumption shall sell any such product within Massachusetts without a valid permit from the Department. No person shall engage in such business in violation of the terms of a valid permit or the requirements of 105 CMR 570.000.

(C) No person shall use water from a particular water source in bottling bottled water or carbonated non-alcoholic beverages unless that source and any treatment of that source have a current approval from the Department or the relevant out-of-state jurisdiction.

(D) No person shall sell or exchange, deliver, advertise, offer, or expose for sale or exchange, or attempt to deliver, or have in his possession with intent to do so, any carbonated non-alcoholic beverage or water, whether carbonated or non-carbonated, for human consumption unless the manufacturer and bottler thereof is the holder of a permit issued pursuant to 105 CMR 570.017 then in full force.

(E) A person who desires to operate a plant within Massachusetts for manufacturing or bottling carbonated non-alcoholic beverages or water, whether carbonated or non-carbonated, shall submit an application for a permit to the board of health of the city or town where the plant is or is to be located, on a form provided by the board of health and approved by the Department. A person who is engaged outside Massachusetts in the business of manufacturing or bottling carbonated non-alcoholic beverages or water, whether carbonated or non-carbonated, and who wishes to sell such products in Massachusetts shall submit an application for a permit to the Department, on a form provided by the Department.
(1) All applicants shall also submit:
(a) The appropriate fee. In-state applicants shall submit the fee with the application. Out-of-state applicants shall submit the fee upon notification by the Department;
(b) For out-of-state plants, proof of licensure or approval from the relevant out-of-state jurisdiction, and a copy of a report of the most recent inspection of the plant completed within the preceding twelve months by the relevant authorities in the out-of-state jurisdiction; and
(c) Any other information required by the application form.
(2) All applicants who manufacture bottled water shall also submit:
(a) Results of analyses of the source water as required by 105 CMR 570.009(A)(1)(d);
(b) Results of analyses of finished products as required by 105 CMR 570.009(A)(2)(d); and
(c) One label for each container size and brand name of the product that is sold or proposed to be sold.

(F) Only a person who complies with the requirements of 105 CMR 570.000 shall be entitled to receive and retain a permit. A permit shall be valid only for the permit holder indicated on the permit and only for the location indicated on the permit.

(G) All permits issued by a board of health to a bottled water plant shall bear a permit number consisting of an abbreviation of the name of the city or town and a unique identifying number. All permits issued by the Department to a bottled water plant shall bear a unique permit number.

(H) A permit shall remain in effect for the period of time specified by statute.

(I) A permit may be renewed by applying to the board of health or Department at least 30 days prior to the expiration of the permit. Application for renewal shall be made in writing on a form provided by the board of health or Department.

(J) No permit holder shall transfer or assign a permit in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any company. No person shall operate pursuant to a permit transferred or assigned by a prior permit holder.

(K) Operating Without a Permit
(1) The board of health or Department may inspect any facility for which it has a reasonable belief contains a bottling operation.
(2) The board of health or Department may deny an application for a permit when the applicant was previously operating a bottling plant, or any type of food processing operation, without a required permit or license.
(3) Operation of a plant that is subject to a permit pursuant to M.G.L. c. 94, § 10A, without a permit, shall subject a person to a fine of not more than the amount specified by statute. The superior court shall have jurisdiction to enjoin the operation of a plant without a permit.
(4) The board of health or Department may take such other steps as required to bring a plant operating without a permit into compliance or to terminate the operation of the plant, in order to protect the health and safety of the public.

570.018: Notification to the Department and the Board of Health

(A) Mailing Address. Each applicant and permit holder shall provide the board of health or Department with its complete and correct mailing address. Each applicant and permit holder shall notify the board of health or Department within seven calendar days of the change of its mailing address. The address provided to the board of health or Department shall be deemed the appropriate address for the service of all orders and notices from the board of health or Department.

(B) Change of Ownership, Name, Location or Water Source
(1) Change of Ownership. A permit holder shall notify the board of health or Department prior to, or within ten days after, a change of ownership. The new owner shall submit to the board of health or Department an application for a new permit. If the new owner submits a complete application for a new permit within ten days after the change of ownership, the existing permit shall not expire until the application for a new permit has been finally determined by the board of health or Department.
(2) Change of Name. A permit holder shall notify the board of health or Department at least 30 days prior to any change of the name of the plant. The permit holder shall submit to the board of health or Department an application for an amended permit, together with written documentation reflecting the change of name.
(3) Change of Location. A permit holder shall notify the board of health or Department at least 30 days prior to a change of location of the plant, and shall relinquish its permit upon closure of

the plant at the former location. The permit holder shall submit to the board of health or Department an application for a new permit, and shall not operate until said permit is issued.
(4) Changes Relating to Water Source. Before a water source is substantially modified, or treatment of source water is begun or substantially modified, or a new source is used in addition to any existing approved source(s), approval by the Department must be obtained in accordance with the procedures specified in 105 CMR 570.007(A) or (B).

(C) Remodeling of an In-state Plant. A permit holder shall promptly notify the board of health and the Department any time that a change is made in an in-state plant that could affect the integrity of products, including but not limited to a change in any production line, storage tank, filling equipment, and bottle washing equipment. After notification, the board of health or Department may inspect the plant to verify compliance with 105 CMR 570.000.

(D) Non-Renewal of In-state Permit. If a permit for an in-state plant is not renewed, the board of health shall notify the Department to that effect.

570.019: Inspections

(A) To carry out properly their responsibilities under 105 CMR 570.000 and applicable statutes and to protect properly the health and well-being of the people of the Commonwealth, authorized agents of the appropriate board of health, the Department, and/or DEP, are authorized, as often as is deemed necessary for the enforcement of 105 CMR 570.000, to enter, examine, or survey any plant engaged in a bottling operation and any source of water for such operation. Upon reasonable belief that a person is engaged in a bottling operation without a permit, the appropriate board of health and the Department are authorized to inspect the plant.

(B) Inspections may be random systematic inspections or in response to a specific complaint. An inspection initiated from a specific complaint is not limited to that complaint. At the time of the inspection, the inspector may record all violations.

(C) Agents of the board of health, the Department, or DEP, after identifying themselves, may enter all areas of the premises, at any reasonable time, for the purpose of making an inspection to ascertain compliance with 105 CMR 570.000 and with applicable requirements for water sources. Any reasonable time includes unannounced inspections, which do not require prior notification. Individuals engaged in bottling operations or water source operations shall provide access to authorized inspectors at any reasonable time for inspection of the premises.

(D) When an inspection of a plant is made, the findings shall be recorded on a printed inspection report form, which shall summarize the requirements of 105 CMR 570.000. Boards of health may obtain a prototype of an inspection form from the Department. A board of health may use this form or, subject to approval by the Department, any form consistent with the prototype. Each board of health that has a plant within its jurisdiction shall submit the form it adopts to the Department.

(E) Agents of the board of health, the Department, or DEP may examine all records to determine which are subject to enforcement under 105 CMR 570.000, applicable requirements for water sources, and all relevant statutes. Agents may copy all relevant records.

(F) The permit holder, applicant, or the person in charge at the time of the inspection shall furnish the inspector with all requested records and shall provide the inspector with access to all areas of the premises.

(G) If the permit holder, applicant, or the person in charge at the time of the inspection refuses entry to an authorized inspector, refuses to permit an authorized inspection, or interferes with the board of health, Department, or DEP or any agent thereof, in the performance of its duties, the board of health or Department may:
(1) Seek in a court of competent jurisdiction an administrative search warrant to search/inspect the premises. The warrant application shall apprise the applicant, permit holder, or owner of the premises concerning the nature of the inspection and justification for it. The board of health or Department may seek the assistance of police authorities in presenting the warrant; and/or
(2) Take steps to refuse to issue or renew, suspend or revoke the permit or source approval or to impose fines in accordance with M.G.L. c. 94, §§ 10F or 305A.

570.020: Notice of Violations/Order to Correct

(A) Whenever the board of health or Department finds upon inspection, investigation of a complaint or through information in its possession that an applicant or permit holder is not in compliance with any of the provisions of 105 CMR 570.000, the board of health or Department shall notify the applicant or permit holder of each violation. The notice shall include a statement of the violations found; the provisions of the law relied upon, the level of severity of the violation, when appropriate; a reasonable period of time for correction; and notice that the failure to correct a violation may result in a refusal to issue or renew or
a suspension or revocation of a permit, and/or the imposition of fines.

(B) The reasonable period of time for correction shall be within the discretion of the board of health or Department to establish in each instance, and shall be based on an evaluation of the type and the severity of each violation.

(C) The inspection report shall constitute the Notice of Violations and the Order to Correct all violations so indicated.

(D) The applicant or permit holder shall be responsible for the correction of all violations and the compliance with any order issued pursuant to 105 CMR 570.000 and applicable statutes.

(E) Service of the Notice of Violations/Order to Correct
(1) Service shall be in person to the applicant or permit holder or to the person in charge at the time of the inspection, or by certified mail, return receipt requested.
(2) If served personally, notice is deemed to be issued on the date when the report is delivered personally.

(3) If served by certified mail, return receipt requested, notice is deemed to be issued on the second business day after it is mailed.

(F) Notices requiring corrective action with respect to an in-state water source shall be issued in accordance with DEP policies and procedures and the MOU.

570.021: Plan of Correction

(A) The applicant or permit holder, within ten calendar days of issuance of the Notice of Violations/Order to Correct, shall:
(1) Correct all violations and file a certification of correction with the board of health or Department, and/or
(2) For those items not certified as corrected, file a written plan of correction with the board of health or Department.

(B) Each plan of correction and each certification shall:
(1) State the name of the applicant or permit holder and the name of the individual and address for receipt of notices;
(2) Reference each violation cited, and for each indicate:
(a) The specific corrective action completed and the date the work was completed; and
(b) When corrective action was not yet completed, the specific corrective action planned and the timetable and date for completion, which is in accordance with the date indicated in the Notice of Violations/Order to Correct; and
(3) Include the date and signature of the applicant or permit holder or his or her official designee, sworn to under the pains and penalties of perjury.

(C) If the applicant or permit holder cannot complete the corrective action within the time frame designated in the Notice of Violations/Order to Correct, the applicant or permit holder must petition the board of health or Department in writing for an extension of the time to correct. Any petition to extend the time to correct must be submitted to the board of health or Department prior to the date indicated in the Notice of Violations/Order to Correct for the violation to be corrected. An untimely petition for extension will not be considered unless good cause can be established for the failure to timely file. A petition for an extension of time shall include the reason(s) that the correction cannot be timely completed (e.g. the work requires a permit which will not be issued within the time period granted), including documentary evidence in support and a specific time by which the plant will complete corrections. The board of health or Department shall notify the applicant or permit holder in writing whether an extension of the time is granted and the duration of the extension, if it is granted.

(D) The board of health or Department may reinspect a plant to determine whether the corrections were completed.

(E) If upon review of the plan of correction and/or upon reinspection the board of health or Department finds that an applicant or permit holder remains noncompliant with applicable laws and regulations, the board of health or Department may initiate administrative enforcement procedures as set forth in 105 CMR 570.022 and 570.023, or it may request that the applicant or

permit holder amend and resubmit the plan of correction within ten calendar days of the issuance of the notice or such other time as the board of health or Department may specify for resubmission.

(F) In-state water sources shall take required corrective action in accordance with DEP policies and procedures and the MOU.

570.022: Grounds for Administrative Enforcement Action

(A) Summary Suspension of a Permit without a Prior Hearing
(1) The board of health or Department may, without a prior hearing, suspend a permit if it finds that the permit holder is operating the business in a manner that is or may cause an imminent health hazard.
(2) A summary suspension order shall be in writing and shall be immediately provided to the permit holder or to the person in charge of the plant and a copy shall be posted at the plant. The order shall state:
(a) The reason(s) for the summary suspension;
(b) The violation(s) leading to the determination that the business is operating in a manner that is or may cause an imminent health hazard and the applicable provision(s) of law;
(c) That all operations or one or more operations of the plant shall immediately cease and desist; and
(d) That a hearing shall be afforded pursuant to the procedures established in 105 CMR 570.023(C).
(3) The Order of Summary Suspension shall be effective upon posting of the order at the plant by an authorized agent of the board of health or Department. If the person whose name appears on the permit is not present at the time of such posting, or if the permit holder is a corporation or other firm, a copy of the Order of Summary Suspension shall also be served in accordance with 105 CMR 570.023(B).
(4) The board of health or Department may end the summary suspension at any time if reasons for the suspension no longer exist.

(B) Refusal to Issue a Permit after Opportunity for a Hearing. After providing an opportunity for a hearing, the board of health or Department may refuse to issue a permit based on any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to refuse to issue a permit:
(1) Failure to submit a permit application or supporting documents in accordance with required procedures;
(2) Failure to submit the required permit fee;
(3) Failure to comply with any provision of 105 CMR 570.000;
(4) Denial of entry to agents of the board of health or Department, refusal to provide access to inspect any part of the premises, or any attempt to impede the work of a duly authorized agent or representative of the board of health or Department;
(5) Providing a false or misleading statement to the board of health or Department, or keeping or submitting any misleading or false records or documents required by 105 CMR 570.000 or related law;

(6) The applicant operated the plant or any other plant or food processing facility without a permit or license or after the expiration of a permit or license;
(7) The applicant or, if the applicant is a corporation, a corporate officer or the owner of the plant, has been convicted of, pled guilty or nolo contendere to, or has, in a judicial proceeding, admitted facts sufficient to find that he or she is guilty of a crime relating to the manufacturing, processing, storage, distribution or sale of food or bottled products in connection with a business;
(8) The applicant or, if the applicant is a corporation, a corporate officer or the owner of the plant, has engaged in conduct that endangers the public health;
(9) A plant or food processing facility owned or operated by the applicant is, or was, the subject of a proceeding(s) which is still ongoing or resulted in the suspension, denial, or revocation of a permit or license or refusal to renew the permit or license;
(10) Failure to pay any federal, state or local taxes as required by law, pursuant to M.G.L. c. 62C, § 49A;
(11) Failure to pay fines levied in accordance with M.G.L. c. 94, §§ 10F, 305A or 305C; or
(12) Failure to comply with local regulations/ordinances related to the operation of the plant.

(C) Suspension of a Permit after Opportunity for a Hearing
(1) After providing an opportunity for a hearing, the board of health or Department may suspend a permit to operate a plant or one or more particular operations of the plant if the plant or operation(s) does not comply with any one or more of the requirements of 105 CMR 570.000.
(2) The suspension shall continue until the board of health or Department determines that the required corrections have been made.

(D) Revocation of a Permit after Opportunity for a Hearing
(1) After providing an opportunity for a hearing, the board of health or Department may revoke a permit to operate a plant or may terminate one or more particular operations of the plant if the plant or operation(s) does not comply with any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to revoke a permit or terminate operation(s):
(a) A serious violation or repeated violations of any of the requirements of 105 CMR 570.000;
(b) Denial of entry to agents of the board of health or Department, refusal to provide access to inspect any part of the premises, or any attempt to impede the work of a duly authorized agent or representative of the board of health or Department;
(c) Providing a false or misleading statement to the board of health or Department, or keeping or submitting any misleading or false records or documents required by 105 CMR 570.000 or related law;
(d) The permit holder or, if the permit holder is a corporation, a corporate officer or the owner of the plant, has been convicted of, pled guilty or nolo contendere to, or has, in a judicial proceeding, admitted facts sufficient to find that he or she is guilty of a crime relating to the manufacturing, processing, storage, distribution or sale of products in connection with the permitted business;
(e) The permit holder or, if the permit holder is a corporation, a corporate officer or the owner of the plant, has engaged in conduct that endangers the public health;
(f) Failure to pay any federal, state or local taxes as required by law, pursuant to M.G.L. c. 62C, § 49A; or
(g) Failure to pay fines levied in accordance with M.G.L. c. 94, §§ 10F or 305A.

(2) The revocation of a permit or termination of one or more operations shall be effective for a period of one year from the date of the final order, unless the order states otherwise.

(E) Refusal to Renew a Permit after Opportunity for a Hearing. After providing an opportunity for a hearing, the board of health or Department may refuse to renew a permit if the plant does not comply with any one or more of the following grounds. Each of the following grounds shall constitute full and adequate grounds to refuse to renew a permit:
(1) Any of the grounds specified in 105 CMR 570.022(A);
(2) Any of the grounds specified in 105 CMR 570.022(B);
(3) Any of the grounds specified in 105 CMR 570.022(C); or
(4) Any of the grounds specified in 105 CMR 570.022(D).

(F) Enforcement Actions with Respect to a Water Source
(1) The Department may summarily suspend source approval if the water source presents an imminent health hazard. The procedures for summary suspension shall be as specified in 105 CMR 570.022(A), except that the Department but not the board of health will undertake the procedures; all references to "permit" and "permit holder" shall be replaced by "source approval" and "source owner;" and all references to "plant" shall be replaced by "water source."
(2) The Department may refuse to grant, suspend with notice, or revoke a source approval if the water source fails to comply with any DEP requirement or with any applicable requirement of these regulations. The procedures for such refusal, suspension or revocation shall be as specified in 105 CMR 570.023, except that the Department but not the board of health will undertake the procedures; all references to "permit" and "permit holder" shall be replaced by "source approval" and "source owner;" and all references to "plant" shall be replaced by "water source."
(3) If the source approval is subject to condition(s), the Department may enforce the conditions by issuing an order or by commencing an administrative enforcement action.

570.023: Procedures for Administrative Enforcement Action

(A) Notice of Action
(1) Whenever the board of health or Department determines to suspend with notice, revoke or refuse to issue or renew a permit, it shall issue a Notice of Action. The Notice shall be in writing and shall specify:
(a) The specific reason(s) for which the particular administrative action is to be taken, and the applicable provisions of law;
(b) That the particular administrative action will occur at the end of a specified reasonable time set by the board of health or Department; and
(c) The procedure for requesting a hearing, unless no hearing is required pursuant to M.G.L. c. 30A, § 13.
(2) The Notice shall be served on the permit holder in accordance with 105 CMR 570.023(B).

(B) Service of Orders and Notices of Action
(1) Orders of Summary Suspension and Notices of Action with respect to any other administrative action shall be served by an agent of the board of health or Department on the applicant or permit holder or his or her authorized agent as follows:
(a) By certified mail, return receipt requested; or

(b) In hand service.
(2) If served by certified mail, return receipt requested, notice is deemed to be issued on the second business day after it is mailed.
(3) If served personally, notice is deemed to be issued on the date when the order or notice is delivered personally.
(4) If, and only if, the methods of service specified in 105 CMR 570.023(B)(1) are unsuccessful, service may be made:
(a) By any person authorized to serve civil process by leaving a copy of the order or notice at his or her last and usual place of abode; or
(b) If, and only if, his or her last and usual place of abode is unknown, service may be made by posting the order or notice in a conspicuous place on or about the premises of the plant.

(C) Hearings
(1) Procedures Applicable to all Hearings
(a) The person to whom an Order of Summary Suspension or Notice of Action was directed may request a hearing before the agency that issued it (i.e. the board of health or Department). Such request shall be in writing and must be received by the board of health or Department within ten days of the issuance of the order or notice.
(b) The failure to timely request a hearing constitutes a waiver of the right to a hearing.
(c) Any settlement of any enforcement action commenced under 105 CMR 570.000 shall be final and shall not be subject to judicial review.
(d) A hearing based on an Order of Summary Suspension shall be conducted within 96 hours after the request for a hearing is received by the board of health or Department. If the 96 hour period expires on a weekend day or holiday, the hearing may be held on the next business day. If the parties agree to postpone the beginning of the hearing beyond 96 hours, the hearing may be postponed.
(e) A hearing based on a Notice of Action to suspend, revoke or refuse to issue or renew a permit shall be commenced within a reasonable time period after the request for a hearing is received by the board of health or Department.
(f) Failure to hold a hearing within the time periods specified herein shall not affect the validity of the proceedings.
(g) The applicant or permit holder shall be given an opportunity to be heard and to show why the proposed action should not be taken. Any oral testimony given at a hearing shall be recorded verbatim (tape recording shall suffice).
(h) In the case of summary suspension of a permit, the standard for decision shall be whether the board of health or Department proved by a preponderance of evidence that there existed, immediately prior to or at the time of the suspension, an imminent health hazard.
(i) In the case of a Notice of Action to suspend, revoke or refuse to issue or renew a permit, the standard of decision shall be whether the board of health or Department proved by a preponderance of the evidence that the permit should be suspended, revoked, denied or not renewed, based on relevant facts as they existed at or prior to the time the board of health or Department initiated the action.
(j) The Notice of Violations/Order to Correct shall constitute prima facie evidence of the conditions listed therein.
(2) Hearings by the Department: Additional Provisions

(a) The Department shall conduct all adjudicatory proceedings in accordance with M.G.L. c. 30A and all applicable provisions of 801 CMR 1.00: Standard Adjudicatory Rules of Practice and Procedure.
(b) At the conclusion of the hearing, if the hearing officer finds any single ground for summary suspension, denial, suspension, revocation, or refusal to renew a permit, the hearing officer shall render a recommended decision affirming the decision of the Department.
(c) Public Health Council and Judicial Review
(i) The recommended decision of the hearing officer shall be reviewed by the Commissioner and the Public Health Council. After review, their decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.
(ii) Any applicant, permit holder, or other responsible person who fails to exercise his or her right to a hearing or withdraws the request for a hearing, waives his or her right to administrative review by the Public Health Council. In such cases, the Commissioner shall issue the final agency decision. The failure to request a hearing or the withdrawal of a request for a hearing shall be deemed a failure to exhaust administrative remedies.
(3) Hearings by the Board of Health: Additional Provisions
(a) A board of health that sets a hearing on a specified date rather than requiring the permit holder to request a hearing, satisfies the hearing requirement provided that it gives adequate notice of the hearing date.
(b) After the hearing, the board of health shall make a final decision based upon the complete hearing record, and shall inform the petitioner in writing of the decision. Any single ground for summary suspension, denial, suspension, revocation, or refusal to renew a permit, constitutes adequate grounds for affirming the notice.
(c) Every notice, decision and other record prepared by the board of health in connection with the hearing shall be entered as a matter of public record in the office of the board of health.
(d) A copy of the transcript or tape recording shall be provided upon request, and a reasonable fee may be charged for the cost of providing the copy.
(e) Any person aggrieved by the final decision of the board of health may seek relief in a court of competent jurisdiction in the Commonwealth.

570.024: Embargo of Products

(A) Pursuant to M.G.L. c. 94, § 189A, the Commissioner or his or her agent or the board of health may place an embargo on any product which it finds or has probable cause to believe is adulterated or misbranded provided that:
(1) A written notice is issued to the permit holder or to the person in charge at the plant; and
(2) The notice specifies in detail the reason(s) for the embargo order.

(B) The Commissioner or his or her agent or the board of health shall tag, label, or otherwise identify any product subject to the embargo order. The tag or label shall state that the product:
(1) Is believed to be adulterated or misbranded;
(2) Has been embargoed for ten days; and
(3) Cannot be removed, used, sold or disposed of without permission of the Commissioner or his or her agent or the board of health.

(C) The Commissioner or his or her agent or the board of health shall permit storage of the product under conditions specified in the embargo order, unless storage is not possible without risk to the public health, in which case immediate destruction shall be ordered and accomplished.

(D) If the product subject to embargo is found to be adulterated or misbranded, the Commissioner or his or her agent or the board of health shall take such steps as are necessary, pursuant to M.G.L. c. 94, § 189A, to effect the condemnation and disposal or reconditioning of the product.

(E) If the product subject to embargo is found not to be adulterated or misbranded, it shall be released.

570.025: Criminal Penalties

Pursuant to the applicable provisions of M.G.L. c. 94, §§ 10F or 305A, criminal penalties may be imposed.

570.026: Nonexclusivity of Enforcement Procedures

None of the enforcement procedures contained in 105 CMR 570.000 is mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

[570.027 - 570.029: RESERVED]

570.030: Variance

(A) Upon application, the board of health or Department, within their respective jurisdictions, may vary the application of any provision of 105 CMR 570.000 with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice. The decision of the board of health or Department shall not conflict with the spirit of 105 CMR 570.000.

(B) A copy of each variance granted by the board of health shall be conspicuously posted for 30 days following its issuance, and shall be available to the public at all reasonable hours in the office of the city or town clerk or the office of the board of health while it is in effect. Notice of the grant of each variance shall be filed with the Department, which shall approve, disapprove, or modify the variance within 30 days from receipt thereof. If the Department fails to comment within 30 days, its approval will be presumed. No work shall be done under any variance until the Department approves it or 30 days elapse without its comment, unless the board of health or the Department certifies in writing that an emergency exists.

(C) A copy of any variance shall be available to the public.

570.031: Severability

The provisions of 105 CMR 570.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY
105 CMR 570.000: M.G.L. c. 94, §§ 10E, 192, 305A, 305B; c. 111, § 5.